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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,891	06/24/2003	Kenneth F. Buechler	36671-745.502	4895
Inverness Medical Innovations / WSGR Wilson Sonsini Goodrich & Rosati, P.C.			EXAMINER	
			JUNG, UNSU	
650 Page Mill Road Palo Alto, CA 94304			ART UNIT	PAPER NUMBER
			1641	
			MAIL DATE	DELIVERY MODE
			11/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/603,891	BUECHLER ET AL.			
Office Action Summary	Examiner	Art Unit			
	UNSU JUNG	1641			
The MAILING DATE of this communication appo Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1)⊠ Responsive to communication(s) filed on <u>04 Au</u>	aust 2008				
·= · · <u>-</u>	action is non-final.				
<i>;</i>	· · · · · · · · · · · · · · · · · · ·				
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims	, , ,				
· <u>_</u>	nonding in the application				
4) Claim(s) 1,3,5,7-9,11,13,15,17 and 39-46 is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6) Claim(s) is/are rejected.					
7) Claim(s) is/are objected to.					
8)⊠ Claim(s) <u>1,3,5,7-9,11,13,15,17 and 39-46</u> are s	ubject to restriction and/or election	on requirement.			
Application Papers					
9)☐ The specification is objected to by the Examiner					
10) The drawing(s) filed on is/are: a) acce	pted or b) objected to by the E	Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)	_				
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  Paper No(s)/Mail Date					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)	atent Application				
Paper No(s)/Mail Date 6) Other:					

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## **DETAILED ACTION**

1. Applicant's amendments in the reply filed on August 4, 2008 have been acknowledged and entered. The reply included amendments to claims 1, 3, 8, 11, and 17, cancellation of claims 2, 4, 6, 10, 12, 14, 16, 37, and 38, and addition of new claims 39-46.

2. Claims 1, 3, 5, 7-9, 11, 13, 15, 17, and 39-46 are pending.

## Election/Restrictions

3. The following election of species is required in view of new claim 42 in the reply filed on August 4, 2008.

This application contains claims directed to the following patentably distinct species:

List: Subject-Derived Markers related to Myocardial Injury (claim 42)

- 1. Glycogen phosphorylase-BB
- 2. Annexin B
- 3. B-Enolase
- 4. Heart-type fatty acid binding protein
- 5. S-100ao
- 6. A combination of species listed above (for this selection, applicant is required to select a combination of subject-derived markers selected from the above list)

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 3, 5, 7-9, 11, 13, 15, 17, 39-41, and 43-46 are generic.

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There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are

added after the election, applicant must indicate which of these claims are readable on the elected species.

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

- 4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to UNSU JUNG whose telephone number is (571)272-8506. The examiner can normally be reached on M-F: 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Unsu Jung/ Unsu Jung Patent Examiner Art Unit 1641